

REMARKS

As stated in the Petition for Revival of an Application Unintentionally Abandoned, in order to facilitate prosecution, Applicants are reviving an application filed by another entity (Nixon & Vanderhye) rather than attempting to have their preferred application (filed by Kilpatrick Stockton) reinstated.

In order to have Applicants preferred claims examined, Applicants have canceled Claims 1-18 of the originally filed application and added new Claims 19-38. New Claims 19-38 are duplicates of the claims as filed in the Kilpatrick Stockton Preliminary Amendment of February 12, 2001 (and paid for by Check No. 1301, copy attached as Appendix A). Support for new Claims 19-38 can be found throughout the specification and claims as filed. New Claims 19-38 have been added for the purpose of more clearly defining a structured embodiment, no subject matter is being disclaimed or abandoned and no new matter has been added by these amendments. New Claims 19-38 remove all multiple dependencies from the claims, and place all claims in condition for examination on their merits. These new Claims 19-38 avoid payment of the surcharge for filing multiple-dependent claims.

Applicants would like to draw the Examiner's attention to the Office Action mailed July 3, 2001. That Office Action does not relate to the claims or US Application No. 09/726,630, directed to nimesulide containing topical pharmaceutical compositions. Instead, the Office Action is for US Application No. 09/726,276 and is directed to treating and preventing a physiological disorder associated with an excess of neuropeptide Y.

Applicants respectfully request that a new first Office Action be issued.

VERSION OF AMENDMENTS WITH MARKINGS SHOWING CHANGES

Added text is marked with underline. Deleted text is marked with [square brackets].

Amendments in the Specification:

In accordance with 37 CFR 1.121(b), the following replacement paragraphs show all the changes made by the foregoing amendment relative to the previous version of the paragraphs.

Page 1, Line 3:

TECHNICAL AREA

Page 1, Line 5:

BACKGROUND OF THE INVENTION

Page 1, Line 24:

SUMMARY OF THE INVENTION

Page 2, before Line 1:

DETAILED DESCRIPTION OF THE INVENTION

Amendments in the Claims:

In accordance with 37 CFR 1.121(c), the following versions of the claims as rewritten by the foregoing amendment show all the changes made relative to the previous versions of the claims.

Claims 1-18 are canceled and new Claims 19-38 are added.

CONCLUSION

Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at (404) 745-2413 is respectfully solicited.

Respectfully submitted,

Suzanne Seavello Shope

By: Suzanne Seavello Shope
Registration No. 37,933

KILPATRICK STOCKTON, LLP
1100 Peachtree Street
Suite 2800
Atlanta, Georgia 30309-4530
(404) 815-6500
(404) 541-3389 (Facsimile)
Our File: 47513-0100 (253113)

09/762,630

Amendment + Response to Office Action

Page 8 A1

APPENDIX A

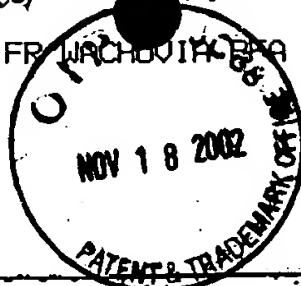
09/762,630 Amendment + Response to Office Action, Page A2

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Page 1 of 1



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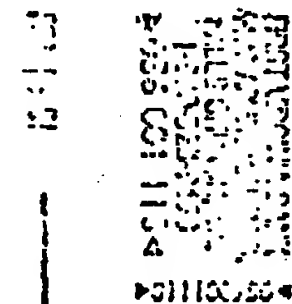
KILPATRICK STOCKTON LLP. OPERATING ACCOUNT 1100 Peachtree Street Atlanta, Georgia 30309-4530		DATE 02-12-01	WACHOVIA Wachovia Bank of Georgia, N.A. Atlanta, GA 30383	NO. 1301 64-1 010
PAY FOUR HUNDRED FIFTY-NINE AND 00/100 Dollars		\$*****459.00		
TO THE ORDER OF Commissioner of Patents & Trademarks		210353871 501 4019 WACHOVIA BANK OF GEORGIA, N.A. TWO SIGNATURES REQUIRED OVER \$2,500 <i>Carl S. McCall</i>		
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Check Number: 1301

Bank ID: 2

Check Date: 02/12/2001

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Amount and Check Information

Status: CLEARED

Amount: 459.00

Batch ID: 02/2001EPA

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OFFICE OF PETITIONS

#15

U9/762630
JC02 Rec'd PCT/PTO 12 FEB 2001

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
EMBIL ET AL.)	
Serial No. CONCURRENTLY HEREWITH)	Art Unit: To be Assigned
(National Phase of PCT/IB99/01460))	
For: NIMESULIDE CONTAINING TOPICAL)	Examiner: To be Assigned
PHARMACEUTICAL COMPOSITIONS)	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Please enter the following amendments in the patent application identified above, before calculating the total amount of filing fee required to enter the national phase for that application.

In the Specification:

- Please insert the phrase -- TECHNICAL AREA -- at page 1, line 3.
- Please insert the phrase -- BACKGROUND OF THE INVENTION -- at page 1, line 5.
- Please insert the phrase -- SUMMARY OF THE INVENTION -- at page 1, line 24.
- Please insert the phrase -- DETAILED DESCRIPTION OF THE INVENTION -- at page 2, before line 1.



In the claims

Cancel claims 1-18.

Add new claims 19-38.

We claim:

19. A composition comprising nimesulide and 17% to 59% by weight of a glyceryl monoolein-solvent-phase, wherein the nimesulide is in the glyceryl monoolein-solvent-phase.
20. The composition of claim 19, wherein glyceryl monoolein-solvent phase has a liquid crystal structure.
21. The composition of claim 19, wherein the nimesulide comprises 0.1% to 5% by weight of the composition.
22. The composition of claim 19, further comprising a non-aqueous solvent.
23. The composition of claim 22, wherein the non-aqueous solvent is selected from the group consisting of diethylene glycol monoethyl ether (DGME) and ethanol.
24. The composition of claim 22, further comprising a gelling agent.
25. The composition of claim 24, wherein the gelling agent is hydroxypropylcellulose.
26. A process, comprising:
 - a. dissolving nimesulide in a non-aqueous solvent;
 - b. heating the nimesulide and the non-aqueous solvent of step a to 30° to 90°C;
 - c. heating glyceryl monoolein to 35° to 55°C;

- d. mixing the nimesulide and the non-aqueous solvent of step a with the glyceryl monoolein of step c; and,
- e. allowing the mixture of step d to cool to room temperature with constant agitation.

27. The process of claim 26, wherein a gelling agent is added at a step selected from the group consisting of step a, step c, step d and step e.

28. A process comprising:
- a. dissolving glyceryl monoolein in a non-aqueous solvent;
 - b. heating the glyceryl monoolein and the non-aqueous solvent of step a to 30° to 90°C;
 - c. mixing nimesulide into the glyceryl monoolein and the non-aqueous solvent of step b; and,
 - d. allowing the mixture of step c to cool to room temperature with constant agitation.

29. The process of claim 28, wherein a gelling agent is added at a step selected from the group consisting of step a, step c and step d.

30. A method, wherein a composition comprising nimesulide and 17% to 59% by weight of a glyceryl monoolein-solvent-phase, wherein the nimesulide is in the glyceryl monoolein-solvent phase, is administered to an animal in need of treatment for an indication selected from the group consisting of pain, inflammation and stiffness in amount effective to treat the animal.

31. The method of claim 30, wherein glyceryl monoolein-solvent phase has a liquid crystal structure.

32. The method of claim 30, wherein the nimesulide comprises 0.1% to 5% by weight of the composition.

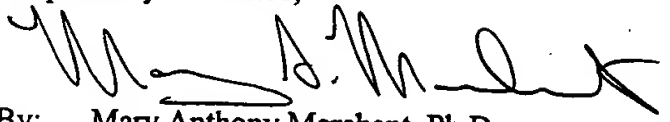
33. The method of claim 30, further comprising a non-aqueous solvent.
34. The method of claim 33, wherein the non-aqueous solvent is selected from the group consisting of diethylene glycol monoethyl ether (DGME) and ethanol.
35. The method of claim 30, further comprising a gelling agent.
36. The method of claim 35, wherein the gelling agent is hydroxypropylcellulose.
37. The method of claim 30, wherein the composition is administered in a form selected from the group consisting of a gel, a solution, an ointment and a spray.
38. The method of claim 37, wherein the composition is administered in the form of a gel.

REMARKS

To facilitate prosecution, Applicants have canceled claims 1 and 18 and added new claims 19-38. Support for new claims 19-38 can be found throughout the specification and claims as filed. New claims 19-38 have been added for the purpose of more clearly defining a structured embodiment, no subject matter is being disclaimed or abandoned and no new matter has been added by these amendments. New claims 19-38 remove all multiple dependencies from the claims, and place all claims in condition for examination on their merits. These new claims 19-38 avoid payment of the surcharge for filing a multiple-dependent claims.

Applicants respectfully requests entry of this preliminary amendment before examination of the application.

Respectfully submitted,


By: Mary Anthony Merchant, Ph.D.
Registration No. 39,771

KILPATRICK STOCKTON, LLP
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, GA 30326
(404) 949-3999
(404) 949-3990 (Facsimile)
Our File: 47513-0100 (253113)

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18 99 / 1460 09/762630

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NP10 8QQ

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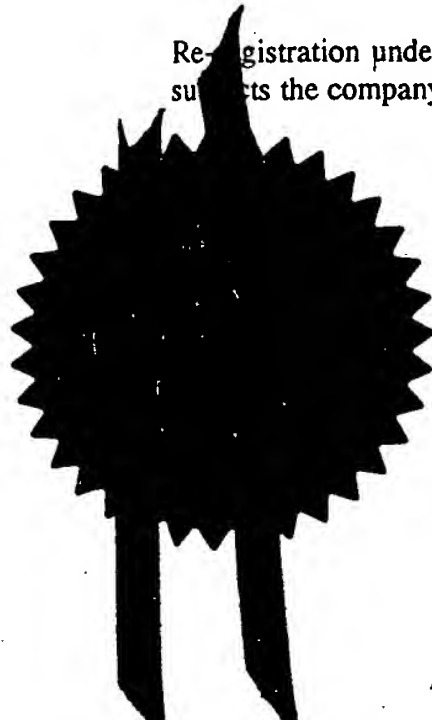
I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



P. Mahoney

Signed

Dated 17 August 1999

JC06 Rec'd PCT/PTO 12 FEB 2001

FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (Rev. 1-98)		Attorney's Docket Number 47513-253113 (0100)
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. Application No. (if known, see 37 CFR 1.5) 09/762630
International Application No. PCT/IB99/01460	International Filing Date 12.08.99 (12 August 1999)	Priority Date Claimed 12.08.98 (12 August 1998)
Title of Invention NIMESULIDE CONTAINING TOPICAL PHARMACEUTICAL COMPOSITIONS		
Applicant(s) for DO/EO/US EMBIL, Koral FIGUEROA, Ray		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). 4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> A translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
Items 11. to 16. below concern document(s) or information included:		
11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 14. <input type="checkbox"/> A substitute specification. 15. <input type="checkbox"/> A change of power of attorney and/or address letter. 16. <input type="checkbox"/> Other items or information:		
Express Mail Label No. EL329854525US		Date: February 12, 2001
Page 1 of 2		

JC02 Rec'd PCT/PTO

12 FEB 2001

U.S. 09/762630	International Application No. CT/IB99/01460	Attorney's Docket Number 47513-253113 (0100)
17. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$970.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$840.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$760.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$670.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$96.00		CALCULATIONS PTO USE ONLY
ENTER APPROPRIATE BASIC FEE AMOUNT =		\$840
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$
Claims	Number Filed	Number Extra
Total claims	20 - 20 =	0
Independent Claims	4 - 3 =	1
Multiple Dependent Claims (if applicable)		+ 260.00
TOTAL OF ABOVE CALCULATIONS =		\$918
Reduction of 1/2 for filing by small entity, if applicable. Applicant claims small entity status.		\$459
SUBTOTAL =		\$918
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		\$
TOTAL NATIONAL FEE =		\$
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		\$
TOTAL FEES ENCLOSED =		\$459
		Amount to be refunded: \$
		charged: \$
a. <input checked="" type="checkbox"/> A check in the amount of \$459 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. 11-0855 in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 11-0855. A duplicate copy of this sheet is enclosed.		
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.		
SEND ALL CORRESPONDENCE TO: Leona G. Young, Ph.D. Kilpatrick Stockton, LLP 2400 Monarch Tower, 3424 Peachtree Road, N.E. Atlanta, Georgia 30326 Telephone: 404-949-2400		
Mary Anthony Merchant, Reg. No. 39,771		
FORM PTO-1390 (Rev. 1-98) adapted		Page 2 of 2

DECLARATION AND POWER OF ATTORNEY

Attorney's Docket No. 47513-0100 (253113)

In re Application of: Koral Embil and Ray Figueroa
As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: Nimesulide Containing Topical Pharmaceutical Compositions, the specification of which:

☒ is attached hereto.

☐ was filed on _____ as Application No. _____ (if applicable) and was amended on _____.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I do not know and do not believe that the same was ever known or used by others in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to the date of this application. I further state that the invention was not in public use or on sale in the United States of America more than one year prior to the date of this application. I understand that I have a duty of candor and good faith toward the Patent and Trademark Office, and I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) of the foreign application(s) for patent or inventor's certificate listed below, and have also identified below any foreign application for patent or inventor's certificate disclosing subject matter in common with the above-identified specification and having a filing date before that of the application on which priority is claimed:

Application No.	Country	Filing Date	Priority Claimed Under 35 USC §119
9817573.0	GB	12 August 1998	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

(Application No.)	(Filing Date)	(Application No.)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter disclosed and claimed in the present application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status: patented, pending, abandoned

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

POWER OF ATTORNEY: The following attorneys are hereby appointed to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Customer Number 23594

Direct all correspondence to: Customer Number 23594

Direct telephone calls at 404-949-3999, to Leona G. Young, Ph.D.

AFFIX BAR
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Full name of sole or first inventor: Koral Embil	Citizenship: T.C.
Inventor's signature: [Signature]	Date: FEBRUARY 12, 2001
Residence and Post Office Address: Bifazane Sokok No: 40, Bomonti, Sisli 80630, Istanbul, Turkey	

☒ Additional inventors are being named on separately numbered sheets attached hereto.

Attorney Docket No.: 47513-0100 (253113)
Title: Nimesulide Containing Topical Pharmaceutical Compositions
Page 2

Full name of second inventor, if any: Ray Figueroa	Citizenship: United States of America
Inventor's signature <i>Ray Figueroa</i>	Date: 2-9-01
Residence and Post Office Address: 8424 N.W. South River Drive, Medley, Florida 33166	

FEB. 26. 2002 3:41PM

KILPATRICK STOCKTON

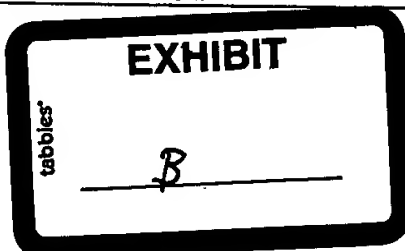
NO. 1355 P. 5/15

KILPATRICK STOCKTON LLP OPERATING ACCOUNT 1100 Peachtree Street Atlanta, Georgia 30309-4630	DATE 02-12-01	WACHOVIA Wachovia Bank of Georgia, N.A. Atlanta, GA 30383	NO. 1301
FOUR HUNDRED FIFTY-NINE AND 00/100 Dollars		\$ 459.00	
Commissioner of Patents & Trademarks		VOID AFTER 120 DAYS TWO SIGNATURES REQUIRED OVER \$5,000 <i>Pat S. McCall</i>	

13010610000101

13815124

FORM PTO-1390 (REV 11-2000)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	INVENTOR'S DOCKET NUMBER 888-50
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) 09/762,630
INTERNATIONAL APPLICATION NO. PCT/IB99/01460	INTERNATIONAL FILING DATE 12 August 1999	PRIORITY DATE CLAIMED 12 August 1998
TITLE OF INVENTION NIMESULIDE CONTAINING TOPICAL PHARMACEUTICAL COMPOSITIONS		
APPLICANT(S) FOR DO/EO/US EMBIL et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The U.S. has been elected by the expiration of 19 months from the priority date (Article 31). 5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> A English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
Items 11 To 20 below concern document(s) or information included:		
11. <input type="checkbox"/> An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98. 12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included. 13. <input type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input type="checkbox"/> Other items or information.		



U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) 09/762,630		INTERNATIONAL APPLICATION NO. PCT/IB99/01460		ATTORNEY'S DOCKET NUMBER 888-50	
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21. ☒ The following fees are submitted:

BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5):	CALCULATIONS	PTO USE ONLY
-- Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	\$1000.00	
-- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	\$860.00	
-- International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO	\$710.00	
-- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)	\$690.00	
-- International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)	\$100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =		
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).		
		\$ 0.00
		\$ 0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total Claims	20	-20 = 0
Independent Claims	3	-3 = 0
MULTIPLE DEPENDENT CLAIMS(S) (if applicable)		\$270.00
TOTAL OF ABOVE CALCULATIONS =		\$ 0.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.		
		\$ 0.00
SUBTOTAL =		\$ 0.00
Processing fee of \$130.00, for furnishing the English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(f)).		
		\$ 0.00
TOTAL NATIONAL FEE =		\$ 0.00
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property		
Petition for one month extension of time		\$ 40.00
		\$ 110.00
TOTAL FEES ENCLOSED =		\$ 150.00
		Amount to be:
		refunded \$
		Charged \$

a. ☒ A check in the amount of \$150.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 14-1140 in the amount of \$_____ to cover the above fees. A duplicate copy of this form is enclosed.

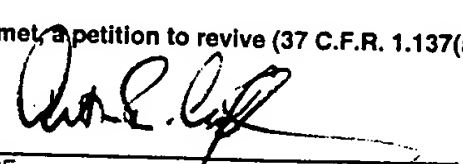
c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed.

d. ☒ The entire content of the foreign application(s), referred to in this application is/are hereby incorporated by reference in this application.

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

NIXON & VANDERHYE P.C.
1100 North Glebe Road, 8th Floor
Arlington, Virginia 22201-4714
Telephone: (703) 816-4000


SIGNATURE

Arthur R. Crawford
NAME

25,327 April 10, 2001
REGISTRATION NUMBER Date

888-50
10241.3

Nixon & Vanderhye P.C. (10/99)
(Domestic Non-Assigned/Foreign) Page 1

RULE 63 (37 C.F.R. 1.63)
INVENTORS DECLARATION FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

As a below named inventor, I hereby declare that my residence, mailing address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

NIMESULIDE CONTAINING TOPICAL PHARMACEUTICAL COMPOSITIONS

the specification of which (check applicable box(es)):

☐ is attached hereto
☒ was filed on February 12, 2001 as U.S. Application Serial No. 09/762,630 (Atty Dkt. No. 888-50)
☒ was filed as PCT International application No. PCT/IB99/01460 on 12 August 1999
and (if applicable to U.S. or PCT application) was amended on _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose to the Patent Office all information known to me to be material to patentability as defined in 37 C.F.R. 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed or, if no priority is claimed, before the filing date of this application:

Priority Foreign Application(s):

Application Number

Country

Day/Month/Year Filed

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

Application Number

Date/Month/Year Filed

I hereby claim the benefit under 35 U.S.C. 120/365 of all prior United States and PCT international applications listed above or below:

For U.S./PCT Application(s):

Application Serial No.

Day/Month/Year Filed

Status: patented
pending, abandoned

PCT/IB99/01460

12 August 1999

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. And on behalf of the owner(s) hereof, I hereby appoint NIXON & VANDERHYE P.C., 1100 North Glebe Rd., 6th Floor, Arlington, VA 22201-4714, telephone number (703) 816-4000 (to whom all communications are to be directed), and the following attorneys thereof (of the same address) individually and collectively owner's/owners' attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent: Larry S. Nixon, 25640; Arthur R. Crawford, 25327; James T. Hosmer, 30184; Robert W. Faris, 31352; Richard G. Besho, 22770; Mark E. Nusbaum, 32348; Michael J. Keenan, 32106; Bryan H. Davidson, 30251; Stanley C. Spooner, 27393; Leonard C. Mitchard, 29009; Duane M. Byers, 33363; Jeffery H. Nelson, 30481; John R. Lastova, 33149; H. Warren Burnam, Jr., 29366; Mary J. Wilson, 32955; J. Scott Davidson, 33489; Alan M. Kagen, 36178; Robert A. Molan, 29834; B. J. Sadoff, 36663; James D. Berquist, 34776; Updeep S. Gill, 37334; Michael J. Shea, 34725; Donald L. Jackson, 41090; Michelle N. Lester, 32331; Frank P. Presta, 19828; Joseph S. Presta, 35329; Joseph A. Rhoa, 37515; Raymond Y. Mah, 41426; Chris Comptzlis, 31097. I also authorize Nixon & Vanderhye to delete any attorney names/numbers no longer with the firm and to act and rely solely on instructions directly communicated from the person, assignee, attorney, firm, or other organization sending instructions to Nixon & Vanderhye on behalf of the owner(s).

1-00 Inventor's Signature: Koral Date: _____

Inventor:

(first)

MI

EMBIL

(last)

Turkey
(citizenship)

Residence: (city)

Istanbul

(state/country) Turkey

Mailing Address:

c/o Embil Pharmaceutical Company Limited, P. O. Box 226, Sisli, Istanbul, Turkey

(Zip Code)

80223

2-00 Inventor's Signature: Ray Date: 3/26/01

Inventor:

(first)

MI

FIGUEROA

(last)

United States
(citizenship)

Residence: (city)

Medley

(state/country) Florida

Mailing Address:

c/o R.F. Technology Consultants, Inc. 8242 N.W. South River Drive, Medley, Florida

(Zip Code)

33166

☐ See attached sheet(s) for additional inventor(s) information!!



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE TECH CENTER 1600/2900

In re Application of:)
Embil et al.)
Serial No. 09/762,630)
Filed: February 12, 2001)
For: Nimesulide Containing Topical)
Pharmaceutical Compositions)

#5
GR1
6/29/01

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

The citation of information on the attached Form PTO/SB/08 is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each cited item is enclosed.

The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicant may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

Respectfully submitted,

Suzanne Seavello Shope

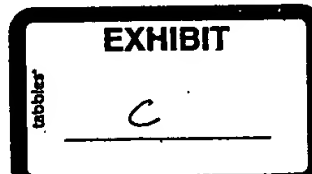
Suzanne Seavello Shope
Reg. No. 37,933

KILPATRICK STOCKTON LLP
2400 Monarch Tower
3424 Peachtree Road, N.E.
Atlanta, Georgia 30326
(404) 949-3999
Our Docket: 47513-0100 (47513-253113)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 13, 2001.

Suzanne Seavello Shope
Suzanne Seavello Shope - Reg. No. 37,933

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Substitute for Form 1449/A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet	1	of	1
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Complete if Known

Application Number	09/762,630
Filing Date	February 13, 2001
First Named Inventor	Koral Embi
Group Art Unit	1614
Examiner Name	
Attorney Docket Number	47513-0100 (47513-253113)

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

Date Considered

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.



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Interview Summary	Application No.	Applicant(s)
	09/762,630	EMBIL ET AL.
	Examiner	Art Unit
	Dwayne C Jones	1614

All participants (applicant, applicant's representative, PTO personnel):

- (1) Dwayne C Jones. (3) _____
(2) Mr. James T. Hosmer. (4) _____

Date of Interview: 26 February 2002.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: All pending.

Identification of prior art discussed: N/A.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: confirmed the abandoned status of this application.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

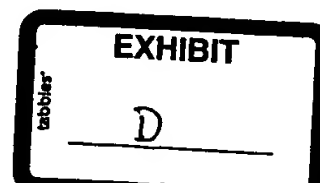
Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

U.S. Patent and Trademark Office
PTO-413 (Rev. 03-98)

Interview Summary

Paper No. 8.



#10



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/762,630	Koral Embil	888-50

INTERNATIONAL APPLICATION NO.

PCT/IB99/01460

I.A. FILING DATE

PRIORITY DATE

08/12/1999

Nixon & Vanderhye
8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

CONFIRMATION NO. 6577



OC000000007719975

Date Mailed: 03/26/2002

NOTICE OF CANCELLATION OF ASSIGNED SERIAL NUMBER

Documents filed under 35 U.S.C. 371 to enter the national stage before the US Designated/Elected Office were received by the US Patent and Trademark Office on 2/12/01 and assigned serial number

9/762630

Documents filed later under 35 U.S.C. 371 and 37 CFR 1.494 or 1.495 were received on 2/12/01 and assigned serial number 9/762776.


The assigned serial number 9/762776 has been cancelled and other assigned serial number should be used when filing papers in the Patent and Trademark Office.

Note: 09/762630 - currently abandoned

Applicant will be receiving further communications concerning 35 U.S.C. 371 in due course.

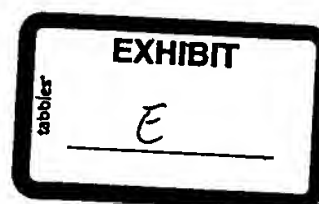
Applicant is reminded that any communication mailed to the United States Patent and Trademark Office must be directed to the address and include the U.S. application no. in the heading above (37 CFR 1.5).

DONNA S GREENE


Telephone: (703) 305-3619

PART 3 - OFFICE COPY

FORM PCT/DO/EO/908 (Canceled Application Number)



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The U.S. Patent & Trademark Office official Mailroom stamp affixed hereto, acknowledges receipt of the items checked below:

Application No.: Filed Concurrently Filing Date: February 12, 2001

Inventor: Koral Embil and Ray Figueroa

Title: NIMESULIDE CONTAINING TOPICAL PHARMACEUTICAL COMPOSITIONS

Enclosures: Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing Under 35 U.S.C. 371, 2 pages; Preliminary Amendment; Declaration and Power of Attorney, 2 pages; check - \$459.00

Docket No.: 47513-0100 (253113)
Atty/Sec'y: LGY/BB/lcb
Date Mailed: February 12, 2001

09/762630

SCANNED
4/4

4/4



SM 4/4/02 253113



The U.S. Patent & Trademark Office official Mailroom stamp affixed hereto,
acknowledges receipt of the items listed below:

Application No: 09/762,630

Application Date.: February 12, 2001

Inventor: Koral Embil et al.

For: Nimesulide Containing Topical Pharmaceutical Compositions

Papers Submitted: Power of Attorney or Authorization of Agent of
Ramon Figueroa, Revocation of Power of Attorney or

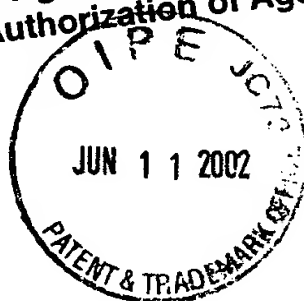
Authorization of Agent of Ramon Figueroa

Power of Attorney or Authorization of Agent of Koral Embil,
Revocation of Power of Attorney or Authorization of Agent of
Koral Embil

Docket No.: 47513-0100 (253113)

Date Mailed June 5, 2002

Atty/Sec'y: JAM:ckf



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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT	Application Number	09/762,630
	Filing Date	February 12, 2001
	First Named Inventor	Koral Embil
	Title	Nimesulide Containing Topical Pharmaceutical Compositions
	Group Art Unit	1614
	Examiner Name	Dwayne C. Jones
	Attorney Docket Number	47513-0100 (47513-253113)

I hereby appoint:

☒ Practitioners at Customer Number.

OR

☐ Practitioner(s) named below:

Name	Registration Number



23370

PATENT & TRADEMARK OFFICE

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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I am the:

☒ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

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SIGNATURE of Applicant or Assignee of Record

NOV 20 2002

Name

Ramon-Figueroa

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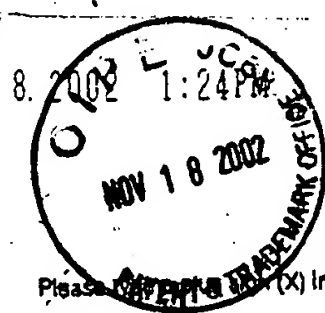
Signature

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of 4 forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



KILPATRICK STOCKTON

NO. 3229 P. 3

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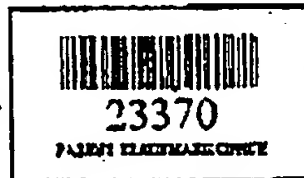
POWER OF ATTORNEY OR AUTHORIZATION OF AGENT	Application Number	09/782,630
	Filing Date	February 12, 2001
	First Named Inventor	Koral Embil
	Title	Nimesulide Containing Topical Pharmaceutical Compositions
	Group Art Unit	1814
	Examiner Name	Dwayne C. Jones
	Attorney Docket Number	47513-0100 (47513-253113)

I hereby appoint:

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OR
☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

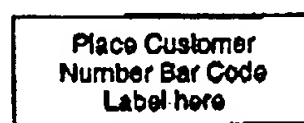


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City	State	ZIP	
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I am the:

☒ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name	Koral Embil
Signature	
Date	May 9, 2002

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 4 forms are submitted.

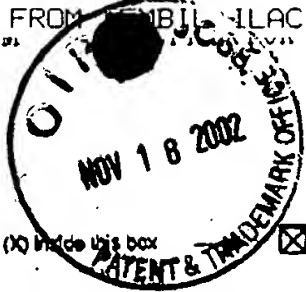
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REVOCATION OF POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	09/762,830
Filing Date	February 12, 2001
First Named Inventor	Koral Embil
Group Art Unit	1614
Examiner Name	Dwayne C. Jones
Attorney Docket Number	47513-0100 (47513-253113)

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application:

☒ A Power of Attorney or Authorization of Agent is submitted herewith.

OR

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OR

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Country				
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I am the:

☒ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
 Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

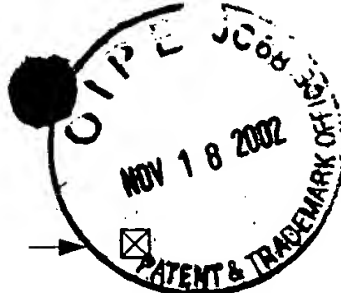
Name	Koral Embil
Signature	
Date	May 9, 2002

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 2 forms are submitted.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REVOCATION OF POWER OF ATTORNEY OR AUTHORIZATION OF AGENT	Application Number	09/762,630
	Filing Date	February 12, 2001
	First Named Inventor	Koral Embil
	Group Art Unit	1614
	Examiner Name	Dwayne C. Jones
	Attorney Docket Number	47513-0100 (47513-253113)

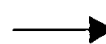
I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application:

☒ A Power of Attorney or Authorization of Agent is submitted herewith.

OR

☐ Please change the correspondence address for the above-identified application to:

☐ Customer Number



Place Customer
Number Bar Code
Label here

OR

<input type="checkbox"/> Firm or Individual Name					
Address					
Address					
City		State		ZIP	
Country					
Telephone		Fax			

I am the:

☒ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Name	Ramon Figueroa
Signature	
Date	5/29/02

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 4 forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

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